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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	10

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/358,937	SPRADLING ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121: As written, the claims encompasses two different methodologies, as follows:

I. Claims 1-24, 28-31, 33, 35, and 36, drawn to methods of maintaining stem cells, classified in class 435, subclass 377.

II. Claims 25-27, drawn to a method of transferal of stem cells to a host, classified in class 435, subclass 325.

III. Claim 32, drawn to a stem cell population, classified in class 435, subclass 325.

IV. Claim 34, drawn to a method of reduction of the number of stem cells or tumor cells, classified in class 435, sublcass 377.

The inventions are distinct, each from the other because of the following reasons:

Invention I is distinct from the Invention II because Invention II, requiring the transfer of a cell population, requires distinct method steps, concerns and considerations not required for the Invention I, and the searches are therefore not contiguous.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case stimulation of BMP signalling has other effects on other cells, such as effects on osteogenesis and stem cells can be maintained by other means, such as by maintenance in serum-containing media.

Inventions I and IV are not related. These inventions have opposite goals and thus require different methods and have different considerations.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells of Invention III can be used for different purposes, such as *in vitro* experimentation.

Invention II is distinct from the Invention IV because Invention II, requiring the transfer of a cell population, requires distinct method steps, concerns and considerations not required for the Invention IV, and the searches are therefore not contiguous.

Invention III is not related to Invention IV. A process for reducing the number of stem or tumor cells can not be used with a process for introducing stem cells into a host.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because each requires a different search, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

3. For Invention I, the claims are directed to two species:

a. *In vitro* methods

b. *In vivo* methods

4. For each Invention, including Invention I, the claims are directed to 5 species, 4 of which are divisible into further species:

a. Methods involving feeder cells

b. Administration of protein

Further species:

i. DPP

ii. BMP-2

iii. BMP-4

c. Transduction with nucleic acid

Further species:

i. DPP

ii. mutant DPP

iii. BMP

iv. DPP-R

d. Gene alteration

Further species:

i. Mad

ii. Med

iii. Dad

iv. Shn

v. Brk

e. Increasing gene expression

i. Hh

ii. Wg

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits for the elected invention to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7, 9, 10, 12-20,and 22-36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via internet email regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**yvonne.eyler@uspto.gov**].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Andres, Ph.D.
August 21, 2000

Yvonne Eyler

YVONNE EYLER, PH.D
PRIMARY EXAMINER